

Regulatory Requirements

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Branches of Federal Government

–Legislative

–Executive

–Judicial

Legislative Branch

- Enacts laws
- Defines agency's regulatory authority
- Defines agency responsibilities
- Tells how agency will perform administrative functions and carry out enforcement activities

Executive Branch

- Headed by the President
- Regulatory agencies are located here
 - Independent
 - Ex. EPA
 - Cabinet appointed
 - Ex. Secretary of Labor
 - Develop regulations and program guidance
 - Carry out enforcement actions
 - US Occupational Safety & Health Review Commission: <http://www.oshrc.gov/index.html>

Judicial Branch

- Laws are interpreted and enforced
- Civil and criminal cases are tried for violations
- Conduct law reviews
- Review regulatory agency actions

The Federal Government can
take no action on any issue
without a law that allows it to act.

Interpreting the Requirements

- Individual Acts are enacted by Congress
 - May refer to short portions or a broader law that was enacted at some period of time
 - May be an original act that created an entirely new regulatory area
 - May be an act that amends an existing law (most common)
 - Body of standing law, or *statutes*

Statutes

- Compiled in two ways
 - Publish separate major laws
 - *As amended*
 - Publish in the United States Code
 - Compilation of law/statutes w/ amendments current up to date of Code publication
 - Organized in *Titles*

Regulations

- Outline specific procedures for the administration and enforcement of laws.
- *Rules* and *Regulations* are synonymous
- Compiled in the **Code of Federal Regulations (CFR)**
- Regulations have the *force of law*

Rulemaking

- Many technical details are determined during the regulatory development process
- We have numerous opportunities to comment on technical details during the rulemaking process
- Can track rulemaking process via *Federal Register*

Typical Rulemaking Process

- Congress enacts law permitting or requiring agency to develop regulations
- Agency develops schedule, effectively puts parties on notice of impending process.
- Agency establishes **docket**
- Agency develops internal regulatory concept

Typical Rulemaking Process

- Agency develops proposed regulation
 - Published in *Federal Register*
 - Preamble – important part
 - *The preamble contains the agency's interpretation of how the regulation will work and is a potential source for any future questions and/or interpretation.*
- Public Hearing – if necessary
- Revise or publish in final form

Challenging The Rules

- Final rule may undergo legal review
 - Agency did not follow administrative procedure requirements or specific requirements in enabling legislation or the agency's own internal rules
 - Based upon erroneous science or economic analysis

Enforcement

- Two kinds of enforcement
 - Administrative: covers all enforcement actions taken by an agency
 - Inspection/administrative review resulting in a violation
 - Official Notice of Violation (NOV)
 - Consent Order
 - Judicial: occurs when the agency takes a case to the courthouse for lawsuit or criminal prosecution.

Summary of Roles

Congress – enacts legislation to create regulatory agencies and give them authority to regulate in specific subject areas.

Regulatory Agencies – develop regulations that describe detailed requirements of regulatory programs, and enforce these programs.

Courts – determine if a regulated entity is civilly or criminally liable for violating laws and regulations; rule on constitutionality of laws and agency conformance to laws and regulations.

How Do You “Navigate” Through Requirements?

- Define your legal scope
 - Federal
 - State
 - Government-owned, contractor-operated
 - Public
 - Private
 - International

How Do You “Navigate” Through Requirements?

- Define your operational scope
 - What requirements apply to safety systems?
 - Very little legal requirements
 - Must identify standards of good practice for guidance
 - What requirements affect my safety system?
 - Environment w/in which the system resides
 - Also must address requirements applicable to hazards the system is designed to mitigate

Conflicts – How Do You Resolve Them?

- Order of precedence
- Examine governing requirement document
 - Scope/applicability
 - CFR – read the Preamble
 - Contracts
 - Provisions for exceptions
 - Waiver
 - Exemption
 - Equivalency

Pedigree of a Requirement

Public Law/Act

Federal Regulation

State/Local Regulations

Contract Requirements

Organization Policy

Work Procedures

How Do You Stay Current?

- CFRs are the body of standing law
 - Updated annually
 - Consult the *Federal Register*
 - Internet access: Government Printing Office; OSHA, EPA, USC, state DEQ & OSHA
- Consensus Standards
 - Professional organization membership
 - Journals, newsletters
 - Networking
- Organizational guidance
 - Internal policies/procedures under documents control

WORK SMART STANDARDS (WSS)

DOE-HDBK-1148-2002

“The Department has deliberately adopted a standards-based approach to safety management that is intended to allow for good judgment in work design and resource allocation.”

DOE Work Smart Standards

- Necessary Standards
 - Legal requirements that must be met
- Sufficient External Standards
 - External guidelines that establish good practice
 - Consensus standards
 - DOE Handbooks, Guides, & Manuals
- Sufficient Internal Standards
 - ES&H Manual
 - Safety System User Manual

Questions?